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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/578,063

05/24/2000

John D. Sharp

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(MBIO99-030)

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7590

02/13/2003

INTELLECTUAL PROPERTY GROUP
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EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 02/13/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/578,063

Applicant(s)

MCCARTHY ET AL.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10,24-26,28-30,33-36 and 38-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10,24-26,28-30,33-36,38-43 and 45-47 is/are rejected.
- 7) ☒ Claim(s) 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED OFFICE ACTION

Applicant's amendment in paper No. 14, filed on 22 July 2002 is acknowledged and entered. Following the amendment, claims 27, 31, 32 and 37 are canceled, claims 8, 9, 24-26, 28, 30 and 35 are amended, and the new claim 47 is added.

Currently, claims 8-10, 24-26, 28-30, 33-36 and 38-47 are pending, and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 27, 31, 32 and 37 are moot as the applicant has canceled the claim.

The objection of claims 8, 9, 24, 30, and 44 for encompassing a non-elected subject matter is withdrawn in view of applicant's amendments.

The rejection of claims 8-10, and 24-46 under 35 U.S.C. 101, for lack of utility is withdrawn in view of applicant's argument.

The rejection of claims 8-10, 28, 30, 33-36, and 38-46, under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's argument and amendment.

Formal Matters:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10, 24-26, 28-30, 33-36 and 38-41 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 8 is indefinite for the recitation of "a TANGO294 activity". It is unclear what activity is intended, and the specification does not define such. Although the specification indicates the lipase activity of TANGO294, it is unclear whether TANGO294 may also possess other activities. As such, the metes and bounds of the claims cannot be determined.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 24-26, 29, 42, 43 and 45 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a isolated polypeptide having SEQ ID NO:47 or 49, or a functional variant thereof, does not reasonably provide enablement for claims to small fragments thereof (claim 8, part a) and claims 24-26 and 29, or variants of the fragments (claims 42 and 43). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are directed to the functional fragments of the TANGO294 having SEQ ID NO:47, 49, or the amino acid sequence encoded by clone EpT294, and % variants of a fragment of SEQ ID NO:47 or 49, wherein the polypeptide fragment can be 40 amino acids in size, or 150 residues with 90% sequence identity, and retains lipase activity. However, the specification merely discloses one human TANGO294 polypeptide with sequence particularity (SEQ ID NO:47 or 49), and indicates said polypeptide has lipase activity. The specification provides neither guidance nor working examples as to how to make the claimed functional fragments or variants thereof. Further, as the TANGO294 is an enzyme, the art generally

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does not acknowledge that a small portion of a large enzyme molecule, for example, 40 amino acid residues in size, would possess enzymatic activity. Given the fact that the TANGO294 polypeptide molecule has 423 amino acid residues, a fragment of 40 amino acids (claim 24, for example) is unlikely to possess the lipase activity. As such, it is unpredictable that the claimed small fragments would possess the biological property, thus undue experimentation would be required prior to using the claimed invention.

Due to the large quantity of experimentation necessary to determine a fragment or a variant thereof having lipase activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art does not acknowledge that a small fragment of a large enzyme molecule, such as 40 amino acids in size, would likely to possess enzyme activity, and the breadth of the claims which embrace a broad class of structural fragments and variants, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 28, 47, 33, 38 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

The claims are directed to an isolated polypeptide having ability to modulate absorption, metabolism or transport of a lipid besides having lipase activity. However, while the specification teaches that the claimed polypeptide is a lipase, there is no written description of such activity in the specification, and the specification provides neither the guidance nor working example to demonstrate the claimed activities of the protein. A lipase, according to the prior art, possesses lipolytic activity, and is not known for its activity on absorption or transport of a lipid. Therefore, it is not predictable that the claimed lipase is directly involved in absorption or transport of lipid. In the absence of the evidence to support such, undue experimentation is required for a skilled artisan to determine the lipid absorption or transport activity of the protein prior using the claimed invention.

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Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 8 recites a cDNA clone EpT294, which was deposited as ATCC Deposit No. 207220. However, the specification fails to provide the deposit statement indicating the deposit material will be readily available to the public without restriction upon issuance of the patent. Such statement would satisfy the enablement requirement of 35 U.S.C. 112.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 10, 28, 47, 30 are rejected under 35 U.S.C. 102(a) as being anticipated by Blanchard et al., US 5,807,726.

Blanchard discloses a polypeptide (SEQ ID NO:3) encoded by a nucleic acid of SEQ ID NO:2 comprises nucleotides 125-1221 of SEQ ID NO:46 of the present invention with 62.8% sequence similarity (84.7% sequence similarity within the coding region for amino acids 37-407 of SEQ ID NO:47 of the instant invention, see appended computer printout of sequence search results). The referenced polypeptide is a dog gastric lipase (column 2, lines 29-37), and comprises amino acids 37-407 of SEQ ID NO:47 of the instant invention with 56.5% sequence similarity. Blanchard's polypeptide, therefore, anticipates claims 8, 10, 28, 47, and 30, as being a variant of SEQ ID NO:47 or 49, and encoded by a nucleic acid hybridizing to a nucleic acid having SEQ ID NO:46 (as claim 8, part b), claims 28 and 30). Further, although Blanchard does not explicitly teach a pharmaceutically acceptable carrier admixed with said polypeptide, it is well known in the art that a purified protein agent is usually used in combination with other

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agent(s), such as dissolving solutions, and can not be used as its crystal form alone. Dissolving solutions, such as water and buffers, are "a pharmaceutically acceptable carrier". Therefore, the reference also anticipates claim 47.

Claims 8, 10, 28, 47 and 30 are also rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (J. Biol. Chem., 1991, 266: 22479-84, provided in the last Office Action, paper No. 10).

Anderson discloses a nucleic acid and a polypeptide encoded thereby (Figure 4), wherein the polypeptide is a human lysosomal acid lipase. The referenced nucleic acid sequence comprises nucleotides 39-1241 of SEQ ID NO:46 of the present invention with 65.3% sequence similarity, and encodes amino acids 2-409 of SEQ ID NO:47 of the instant invention with 83% sequence similarity (see appended computer printout of sequence search results, provided in the last Office Action, paper No. 10). Anderson's polypeptide, therefore, anticipates claims 8, 10, 28, 47 and 30 for the same reasons addressed above.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 33 and 34 are rejected under 35 U.S.C. 102(a) as anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Blanchard et al., US 5,807,726.

Claim 33 requires the functional limitation that the claimed polypeptide has ability to modulate absorption, metabolism or transport of a lipid besides having lipase activity. As addressed above, the referenced sequence anticipates the polypeptide of the instant claim 30, which claim 33 depends from, and has lipase activity, but the reference does not mention the other properties as claimed. The examiner is unable to determine whether the prior art disclosure possesses the non-recited property. With the condition, where the prior art peptide comprises the amino acid sequence that seems to meet the sequence limitation of the polypeptide of claim 33, except that the prior art is silent to the properties claimed, then the burden shifts to the applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977). Further, although Blanchard does not explicitly teach a pharmaceutically acceptable carrier admixed with said polypeptide, it is well known in the art that a purified protein agent is usually used in combination with other agent(s), such as dissolving solutions, and can not be used as its crystal form alone. Dissolving solutions, such as water and buffers, are "a pharmaceutically acceptable carrier". Therefore, the reference would also anticipate claim 34.

Claims 33 and 34 are also rejected under 35 U.S.C. 102(b) as anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Anderson et al. (J. Biol. Chem., 1991, 266: 22479-84) for the same reasons above.

Conclusion:

No claim is allowed.

Claim 44 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

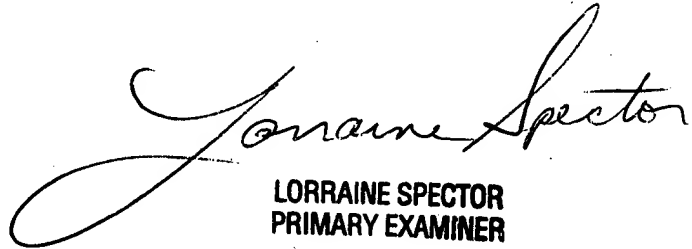
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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
1/8/03